UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------|------------------|
| 10/588,554 | 08/07/2006 | Joel M. Van Gelder | VAN GELDERIA | 8291 |
| BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 | | | EXAMINER | |
| | | | . SZNAIDMAN, MARCOS L | |
| WASHINGTON, DC 20001-5303 | | | ART UNIT | PAPER NUMBER |
| | | | 1609 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | 1 | 10/01/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | | | |
|--|---|--|--|--|--|--|
| | 10/588,554 | VAN GELDER ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Marcos L. Sznaidman | 1609 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on 07 Au 2a) This action is FINAL. 2b) This 3) Since this application is in condition for allowant closed in accordance with the practice under E | action is non-final. see except for formal matters, pro | | | | | |
| Disposition of Claims | | | | | | |
| 4) | vn from consideration. | equirement. | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examiner 10) The drawing(s) filed on is/are: a) access applicant may not request that any objection to the of Replacement drawing sheet(s) including the correction to the original original content of the correction of the original original content or declaration is objected to by the Examiner | epted or b) objected to by the Edrawing(s) be held in abeyance. See on is required if the drawing(s) is obj | e37 CFR 1.85(a). ected to. See 37 CFR 1.121(d). | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some color None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date | 4) Interview Summary (Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other: | te | | | | |

DETAILED ACTION

Restriction Requirement (Compound)

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4, 54-67 and 137-140, drawn to a method for treatment of a disease or disorder caused by or associated with heparanase catalytic activity, comprising administering to a patient an effective amount of an heparanase inhibitor represented by the general formulas [la] and [l'a] (see claim 2).

Group II, claim(s) 1, 6-8, 54-67 and 137-140, drawn to a method for treatment of a disease or disorder caused by or associated with heparanase catalytic activity, comprising administering to a patient an effective amount of an heparanase inhibitor represented by the general formula [Ib] (see claim 6).

Group III, claim(s) 1, 13-15, 54-67 and 137-140, drawn to a method for treatment of a disease or disorder caused by or associated with heparanase catalytic activity, comprising administering to a patient an effective amount of an heparanase inhibitor represented by the general <u>formula [Ic]</u> (see claim 13).

Group IV, claim(s) 1, 16-18, 54-67 and 137-140, drawn to a method for treatment of a disease or disorder caused by or associated with heparanase catalytic activity,

Application/Control Number: 10/588,554

Art Unit: 1609

comprising administering to a patient an effective amount of an heparanase inhibitor represented by the general <u>formula [Id]</u> (see claim 16).

Group V, claim(s) 1, 19-20, 54-67 and 137-140, drawn to a method for treatment of a disease or disorder caused by or associated with heparanase catalytic activity, comprising administering to a patient an effective amount of an heparanase inhibitor represented by the general <u>formula [le]</u> (see claim 19).

Group VI, claim(s) 1, 22-24, 54-67 and 137-140, drawn to a method for treatment of a disease or disorder caused by or associated with heparanase catalytic activity, comprising administering to a patient an effective amount of an heparanase inhibitor represented by the general <u>formula [If]</u> (see claim 22).

Group VII, claim(s) 1, 25-27, 54-67 and 137-140, drawn to a method for treatment of a disease or disorder caused by or associated with heparanase catalytic activity, comprising administering to a patient an effective amount of an heparanase inhibitor represented by the general <u>formula [lq]</u> (see claim 25).

Group VIII, claim(s) 1, 28-30, 54-67 and 137-140, drawn to a method for treatment of a disease or disorder caused by or associated with heparanase catalytic activity, comprising administering to a patient an effective amount of an heparanase inhibitor represented by the general formula [Ih] (see claim 28).

Group IX, claim(s) 1, 31-33, 54-67 and 137-140, drawn to a method for treatment of a disease or disorder caused by or associated with heparanase catalytic activity, comprising administering to a patient an effective amount of an heparanase inhibitor represented by the general <u>formula [li]</u> (see claim 31).

Group X, claim(s) 1, 34-36, 54-67 and 137-140, drawn to a method for treatment of a disease or disorder caused by or associated with heparanase catalytic activity, comprising administering to a patient an effective amount of an heparanase inhibitor represented by the general formula [Iii] (see claim 34).

Group XI, claim(s) 1, 37-39, 54-67 and 137-140, drawn to a method for treatment of a disease or disorder caused by or associated with heparanase catalytic activity, comprising administering to a patient an effective amount of an heparanase inhibitor represented by the general <u>formula [lk]</u> (see claim 37).

Group XII, claim(s) 1, 40-42, 54-67 and 137-140, drawn to a method for treatment of a disease or disorder caused by or associated with heparanase catalytic activity, comprising administering to a patient an effective amount of an heparanase inhibitor represented by the general <u>formula [II]</u> (see claim 40).

Group XIII, claim(s) 1, 43-45, 54-67 and 137-140, drawn to a method for treatment of a disease or disorder caused by or associated with heparanase catalytic activity, comprising administering to a patient an effective amount of an heparanase inhibitor represented by the general <u>formula [lm]</u> (see claim 43).

Group XIV, claim(s) 1, 46-47, 54-67 and 137-140, drawn to a method for treatment of a disease or disorder caused by or associated with heparanase catalytic activity, comprising administering to a patient an effective amount of an heparanase inhibitor represented by the general <u>formula [In]</u> (see claim 46).

Group XV, claim(s) 1, 48-49, 54-67 and 137-140, drawn to a method for treatment of a disease or disorder caused by or associated with heparanase catalytic

Application/Control Number: 10/588,554

Art Unit: 1609

activity, comprising administering to a patient an effective amount of an heparanase inhibitor represented by the general <u>formula [II]</u> (see claim 48).

Group XVI, claim(s) 1, 50-51, 54-67 and 137-140, drawn to a method for treatment of a disease or disorder caused by or associated with heparanase catalytic activity, comprising administering to a patient an effective amount of an heparanase inhibitor represented by the general <u>formula [III]</u> (see claim 50).

Group XVII, claim(s) 1, 52-53, 54-67 and 137-140, drawn to a method for treatment of a disease or disorder caused by or associated with heparanase catalytic activity, comprising administering to a patient an effective amount of an heparanase inhibitor represented by the general <u>formula [IV]</u> (see claim 52).

Group XVIII, claim(s) 136, drawn to a compound selected from the group of compounds herein designated Compounds Nos 12, 18, 27, 37, 48, 50, 61-63, 70, 71, 75, 77, 83-87, 90-96 and 98-107.

The inventions listed as Groups I-XVIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common technical feature in all groups is an heparanase inhibitor. This element cannot be a special technical feature under PCT rule 13.2 because the element is known in the prior art.

Elections

First election for Group I

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Compounds listed in claims 1-4, which correspond to general structures I, Ia and I'a. Applicant is required to elect a single disclosed species (species like methyl, not a genus definition like alkyl).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1-4, 54-67 and 137-140.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species represent structurally divergent chemical compounds, and thus lack the same special technical feature (e.g. when R8 in claim 2 is hydrogen or a complex heterocycle). There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g. searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 112, first paragraph.

First election for Group II

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Compounds listed in claims 1 and 6-8, which correspond to general structures I, and Ib. Applicant is required to elect a single disclosed species (species like methyl, not a genus definition like alkyl).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1, 6-8, 54-67 and 137-140.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species represent structurally divergent chemical compounds, and thus lack the same special technical feature (e.g. when R16 in claim 6 is hydrogen or a complex heterocycle). There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g. searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 112, first paragraph.

First election for Group III

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Compounds listed in claims 1 and 13-15, which correspond to general structures I and Ic. Applicant is required to elect a single disclosed species (species like methyl, not a genus definition like alkyl).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1, 13-14, 54-67 and 137-140.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or

corresponding special technical features for the following reasons: the species represent structurally divergent chemical compounds, and thus lack the same special technical feature (e.g. when R9 in claim 13 is hydrogen or a complex heterocycle). There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g. searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 112, first paragraph.

First election for Group IV

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Compounds listed in claims 1 and 16-18, which correspond to general structures I and Id. Applicant is required to elect a single disclosed species (species like methyl, not a genus definition like alkyl).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims

subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Page 11

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1, 16-18, 54-67 and 137-140.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species represent structurally divergent chemical compounds, and thus lack the same special technical feature (e.g. when R4 in claim 16 is hydrogen or a complex heterocycle). There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g. searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 112, first paragraph.

Application/Control Number: 10/588,554 Page 12

Art Unit: 1609

First election for Group V

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Compounds listed in claims 1 and 19-20, which correspond to general structures I and Ie. Applicant is required to elect a single disclosed species (species like methyl, not a genus definition like alkyl).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1, 19-20, 54-67 and 137-140.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species

represent structurally divergent chemical compounds, and thus lack the same special technical feature (e.g. when R14 in claim 19 is an alkyl chain that could be substituted with nitro or aziridine). There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g. searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 112, first paragraph.

First election for Group VI

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Compounds listed in claims 1 and 22-24, which correspond to general structures I and If. Applicant is required to elect a single disclosed species (species like methyl, not a genus definition like alkyl).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1, 22-24, 54-67 and 137-140.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species represent structurally divergent chemical compounds, and thus lack the same special technical feature (e.g. when R14 in claim 22 is an alkyl chain that could be substituted with nitro or aziridine). There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g. searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 112, first paragraph.

First election for Group VII

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Application/Control Number: 10/588,554

Art Unit: 1609

The species are as follows:

Compounds listed in claims 1 and 25-27, which correspond to general structures I and Ig. Applicant is required to elect a single disclosed species (species like methyl, not a genus definition like alkyl).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1, 25-27, 54-67 and 137-140.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species represent structurally divergent chemical compounds, and thus lack the same special technical feature (e.g. when R'13 in claim 25 is an =O or substituted phenyl). There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g.

searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 112, first paragraph.

First election for Group VIII

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Compounds listed in claims 1 and 28-30, which correspond to general structures I and Ih. Applicant is required to elect a single disclosed species (species like methyl, not a genus definition like alkyl).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

Page 17

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1, 28-30, 54-67 and 137-140.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species represent structurally divergent chemical compounds, and thus lack the same special technical feature (e.g. when R14 in claim 28 is an alkyl chain that could be substituted with nitro or aziridine). There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g. searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 112, first paragraph.

First election for Group IX

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Compounds listed in claims 1 and 31-33, which correspond to general structures I and Ii. Applicant is required to elect a single disclosed species (species like methyl, not a genus definition like alkyl).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1, 31-33, 54-67 and 137-140.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species represent structurally divergent chemical compounds, and thus lack the same special technical feature (e.g. when R13 in claim 31 is an alkyl chain or an heterocycle). There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g. searching different classes/subclasses or electronic resources, or employing different

search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 112, first paragraph.

First election for Group X

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Compounds listed in claims 1 and 34-36, which correspond to general structures I and Ij. Applicant is required to elect a single disclosed species (species like methyl, not a genus definition like alkyl).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1, 34-35, 54-67 and 137-140.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species represent structurally divergent chemical compounds, and thus lack the same special technical feature (e.g. when R9 in claim 34 is H or alkyl substituted by COOH). There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g. searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 112, first paragraph.

First election for Group XI

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Compounds listed in claims 1 and 37-39, which correspond to general structures I and Ik. Applicant is required to elect a single disclosed species (species like methyl, not a genus definition like alkyl).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1, 37-38, 54-67 and 137-140.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species represent structurally divergent chemical compounds, and thus lack the same special technical feature (e.g. when R'9 in claim 27 is an alkenyl chain that could be substituted with nitro or aziridine). There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g. searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 112, first paragraph.

First election for Group XII

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Compounds listed in claims 1 and 40-42, which correspond to general structures I and II. Applicant is required to elect a single disclosed species (species like methyl, not a genus definition like alkyl).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1, 40-41, 54-67 and 137-140.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or

corresponding special technical features for the following reasons: the species represent structurally divergent chemical compounds, and thus lack the same special technical feature (e.g. when R'7 in claim 40 is an alkyl chain that could be substituted with nitro or aziridine). There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g. searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 112, first paragraph.

First election for Group XIII

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Compounds listed in claims 1 and 43-45, which correspond to general structures I and Im. Applicant is required to elect a single disclosed species (species like methyl, not a genus definition like alkyl).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims

subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1, 43-44, 54-67 and 137-140.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species represent structurally divergent chemical compounds, and thus lack the same special technical feature (e.g. when R9 in claim 43 is an alkyl chain that could be substituted with nitro or aziridine). There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g. searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 112, first paragraph.

Application/Control Number: 10/588,554 Page 25

Art Unit: 1609

First election for Group XIV

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Compounds listed in claims 1 and 46-47, which correspond to general structures I and In. Applicant is required to elect a single disclosed species (species like methyl, not a genus definition like alkyl).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1, 46, 54-67 and 137-140.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species

represent structurally divergent chemical compounds, and thus lack the same special technical feature (e.g. when R9 in claim 46 is an alkyl chain that could be substituted with nitro or aziridine). There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g. searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 112, first paragraph.

First election for Group XV

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Compounds listed in claims 1 and 48-49, which correspond to general structure II. Applicant is required to elect a single disclosed species (species like methyl, not a genus definition like alkyl).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1, 48, 54-67 and 137-140.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species represent structurally divergent chemical compounds, and thus lack the same special technical feature (e.g. when R7 in claim 48 is an alkyl chain that could be substituted with nitro or aziridine). There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g. searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 112, first paragraph.

Election for Group XVI

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Application/Control Number: 10/588,554

Art Unit: 1609

The species are as follows:

Compounds listed in claims 1 and 50-51, which correspond to general structure III. Applicant is required to elect a single disclosed species (species like methyl, not a genus definition like alkyl).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1, 50, 54-67 and 137-140.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species represent structurally divergent chemical compounds, and thus lack the same special technical feature (e.g. when R'7 in claim 50 is an alkyl chain that could be substituted with nitro or aziridine). There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a

different field of search (e.g. searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 112, first paragraph.

Election for Group XVII

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Compounds listed in claims 1 and 52-53, which correspond to general structures IV. Applicant is required to elect a single disclosed species (species like methyl, not a genus definition like alkyl).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Page 30

The following claim(s) are generic: 1, 52, 54-67 and 137-140.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species represent structurally divergent chemical compounds, and thus lack the same special technical feature (e.g. when R"7 in claim 52 is an alkyl chain that could be substituted with nitro or aziridine). There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g. searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 112, first paragraph.

Second election for Groups I-XVII

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Diseases or disorders listed in claims 1 and 54-67 and 137-140. Applicant must elect a single disclose species (a single species like liver tumor, not a genus like solid tumor).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1-8, 13-20, 22-67 and 137-140.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species represent structurally divergent chemical compounds, and thus lack the same special technical feature (e.g. when R14 in claim 22 is an alkyl chain that could be substituted with nitro or aziridine). There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g. searching different classes/subclasses or electronic

resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 112, first paragraph.

Election for Group XVIII

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Compounds listed in claim 136. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1136.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species represent structurally divergent chemical compounds, and thus lack the same special technical feature. There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g. searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 112, first paragraph.

Rejoinder Notice

The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process

claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Inventorship Notice

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Application/Control Number: 10/588,554 Page 35

Art Unit: 1609

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcos L. Sznaidman whose telephone number is 571 270-3498. The examiner can normally be reached on Monday through Friday 9 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MLS September 27, 2007

Cocilia J. Tsang
Fory Patent Examiner
Cociliant Control Control